K000578

MAY - 5 2000

Serim™
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510(k) SUMMARY

Serim™ Leukocyte Esterase Test Strips

Submitted by:

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Contact person: Robert J. Carrico

Robert J. Carrico
2/16/2000

Date prepared: February 16, 2000

Device Name:

Trade name: Serim™ Leukocyte Esterase Test Strips
Common name: Leukocyte esterase test strip

Classification name: Leukocyte esterase test for use in peritoneal dialysates

Legally Marketed Equivalent Device:

Serim™ Leukocyte Esterase Test Strip is functionally equivalent to Leukostix Reagent Strips for Urinalysis, K843727. The product was evaluated by comparison to leukocyte counts in peritoneal dialysates determined by light microscopy.

Description of the Serim™ Leukocyte Esterase Test Strip

The Serim Leukocyte Esterase Test Strip consists of a 0.2 x 0.2 inch reagent pad attached to one

end of a white 0.2 x 3.25 inch polystyrene handle. The reagent pad is immersed into a spent peritoneal dialysate, removed immediately and allowed to react for four minutes. Then the reagent pad color is compared to a color chart on the bottle label. The first block is yellow and is marked "Negative". The remaining three blocks have sequentially increasing lavender color and are marked "Trace", "Small" and "Large".

Peritonitis in peritoneal dialysis patients is diagnosed by a combination of clinical and laboratory findings. Two of the following three criteria should be present for diagnosis of peritonitis: 1) symptoms of peritoneal inflamation, 2) cloudy dialysate with elevated white cell count (> 100 cells/μL) due mainly to neutrophils (> 50%) and 3)demonstration of bacteria in the dialysate by Gram's stain or culture (1).

Intended Use:

Spent peritoneal dialysis fluids are routinely examined for cloudiness after they are drained from the peritoneal cavity. Cloudy dialysate can be due to white cell counts above 50 to 100 cells/μL. A cloudy dialysate along with abdominal pain is sufficient reason to begin antibiotic therapy for peritoneal infection.

Cloudy peritoneal dialysate can also be due to fibrin; therefore, a dialysate white cell count should be obtained when possible. Peritonitis is usually associated with an increase in both the number and percentage of neutrophils in dialysate. Sometimes a cloudy dialysate will have a high cell count which is predominately eosinophils or monocytes and these cases do not require antibiotic therapy.

A relatively clear dialysate does not exclude peritonitis. Early in peritonitis the cell count can be elevated but not enough to give a cloudy appearance. Typically the main cell population will be neutrophils and this circumstance can be diagnosed with total and differential cell counts.

Peritonitis must be diagnosed and treated as quickly as possible. A rapid test for leukocytes in peritoneal dialysates can be a useful aid in indicating the need for further testing and initiation of antibiotic therapy.

Technological Comparison to Predicate Device:

Serim Leukocyte Esterase Test Strips measure leukocyte esterase, also called neutrophil elastase, activity in peritoneal dialysate. Granulocytic leukocytes contain esterase(s) that catalyze the hydrolysis of a derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-pyrrole which reacts with a diazonium salt to yield a purple color. The result is read by visual comparison of the strip reagent pad color to a color chart on the bottle label

The chemistry and procedure used for Serim Leukocyte Esterase Test Strips are virtually identical

to those used for Leukostix Reagent Strips for Urinalysis. The difference is Serim Leukocyte Esterase Test Strips are used to test peritoneal dialysates instead of urine.

Statement of Substantial Equivalence

Serim Leukocyte Esterase Test Strips were used to test 102 spent peritoneal dialysates collected from 27 patients during a 5 month period. Strip readings were compared to neutrophil counts in the dialysates as determined by light microscopy. Readings of Trace or higher indicated significant neutrophil counts and the need for further evaluation for diagnosis of peritonitis.

Serim Leukocyte Esterase Test Strips are functionally equivalent to Leukostix Reagent Strips for Urinalysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY - 5 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Robert J. Carrico
Serim Research Corporation
P.O. Box 4002
Elkhart, Indiana 46514

Re: K000578
Trade Name: Serim™ Leukocyte Esterase Test Strips
Regulatory Class: II
Product Code: LJX
Dated: February 17, 2000
Received: February 22, 2000

Dear Mr. Carrico:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000578

Device Name: Serim Leukocyte Esterase Test Strip

Indications For Use:

Serim Leukocyte Esterase Test Strips provide a rapid and convenient means for testing spent peritoneal dialysates for leukocyte esterase activity. The presence of significant esterase activity in dialysates indicates the need for further testing for diagnosis of peritonitis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000578

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)